K113102

DEC 12 2011

Nucletron

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Department of Health and Human Services
Centre of Device and Radiological Health
Office of Device Evaluation
Traditional 510(k) section

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by section 21 CFR 807.92

Submitter of 510(k):

Company name:	Nucletron Corporation
Registration number:	3006624729
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Correspondent:	Michael Paul, Quality Assurance & Regulatory Affairs Manager
Date:	September 15, 2011

New Device Name:

Trade/Proprietary Name:	Oncentra manual Low Dose Rate Treatment Planning v1.0
Common/Usual Name:	Treatment Planning System for Radiation Therapy
Classification Name:	System, Planning, Radiation Therapy Treatment
Classification:	21CFR 892.5050 Class II Product Code MUJ

Legally Marketed Device(s)
Our modified device is based on the legally marketed device cited in the table below:

Manufacturer	Device	510(k) #
Nucletron BV	PLATO Brachytherapy (BPS14)	K983343

Device description:
Oncentra manual Low Dose Rate Brachytherapy v1.0 is a software package designed for treatment planning of manually loaded low dose rate radioactive sources. This software runs on an Oncentra radiation therapy treatment planning system workstation.

Oncentra manual Low Dose Rate Brachytherapy v1.0 is capable of reconstructing the brachytherapy implant from radiographic images or the specification of coordinates, defining the location of the radioactive sources within the implant, and identifying a reference point, e.g.

software program calculates the treatment data which includes dose distributions and treatment/implantation time.

The brachytherapy treatment planning session allows the physician to evaluate the implant prior to insertion of the low dose radioactive sources, e.g. tubes, wires, in order to determine the most optimal dose distribution within the treatment volume. Once the physician approves the treatment plan the implant is manually loaded with radioactive sources. The program provides a variety of plan evaluation tools to assist in the assessment of the implant quality, e.g. dose volume histogram, dose verification to defined points, dose profiles within the implant, etc.

This software program is for manually loaded low dose radioactive sources and does not interface with an external treatment machine, software programs or control units; it strictly provides hard copy output related to the dose distribution, total treatment time, and other treatment related information.

Intended use:

Brachytherapy planning with Oncentra manual Low Dose Rate Treatment Planning is intended for use with brachytherapy procedures, i.e. intercavitary, interstitial, intraluminal including bronchial and surface applicator treatments, involving manually loaded radioactive sources. The software program provides the physician with anatomical and dosimetric information to determine the positioning and loading of the radioactive sources prior to insertion. The software also provides the treatment time and dose distribution for the specific loading. From this information the patient can be treated with radioactive sources.

Summary of the Technical Characteristics
Oncentra manual Low Dose Rate Treatment Planning is the same device as the predicate device with a new user interface and Windows computer platform. The software provides treatment planning data for manually loaded low dose radioactive sources, e.g. wires, tubes and seeds.

Summary of Non- clinical testing
Comparison testing was performed between Oncentra manual Low Dose Rate Treatment Planning and the predicate device. The results demonstrated that the treatment planning output between the two products were within an acceptable range.

Summary of Clinical testing
Clinical testing was not required to demonstrate substantial equivalence.

Conclusion
The Oncentra manual Low Dose Rate Treatment Planning device is substantially equivalent to the cleared predicate device, PLATO Brachytherapy (#K983343).

Sept. 27, 2011
Date

Name: John Lapre
Title: Vice President Research & Development
Nucletron B.V.
Veenendaal, The Netherlands

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

DEC 12 2011

Mr. Michael Paul
QA/RA Manger
Nucletron Corporation
7021 Columbia Gateway Drive, Suite 200
COLUMBIA MD 21046-2133

Re: K113102
Trade/Device Name: Oncentra Manual Low Dose Rate Treatment Planning v1.0
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: October 15, 2011
Received: October 19, 2011

Dear Mr. Paul:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number K113102

Device Name Oncentra manual Low Dose Rate Treatment Planning v1.0

Indications for Use

Brachytherapy planning with Oncentra manual Low Dose Rate Treatment Planning is intended for use with brachytherapy procedures, i.e. intercavitary, interstitial, intraluminal including bronchial and surface applicator treatments, involving manually loaded radioactive sources. The software program provides the physician with anatomical and dosimetric information to determine the positioning and loading of the radioactive sources prior to insertion. The software also provides the treatment time and dose distribution for the specific loading. From this information the patient can be treated with radioactive sources.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 subpart D) (Part 21 CFR 801 subpart C)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)